

**TRADE SECRET**

***Study Title***

H-28548: 21-Day Chronic, Static-Renewal Toxicity Test with the Cladoceran,  
*Daphnia magna*

**TEST GUIDELINES:** U.S. EPA Ecological Effects Test Guidelines  
OPPTS 850.1300 (1996)

OECD Guideline for the Testing of Chemicals  
Section 2 (Part 211) (1998)

**AUTHOR:** Robert A. Hoke, Ph.D.

**STUDY COMPLETED ON:** December 18, 2008

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
for Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-17751-254

**WORK REQUEST NUMBER:** 17751

**SERVICE CODE NUMBER:** 254

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

*Study Title*

H-28548: Inhalation Acute Exposure With Anatomic Pathology Evaluation in Rats

**AUTHOR:** Thomas A. Kegelman, A.A.

**STUDY COMPLETED ON:** May 11, 2009

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-17751-723

**WORK REQUEST NUMBER:** 17751

**SERVICE CODE NUMBER:** 723

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

**FINAL REPORT**

Volume 1 of 8  
(Text, Figures 1-16 and Tables 1-69)

**STUDY TITLE**

A 90-DAY ORAL (GAVAGE) TOXICITY STUDY OF H-28548 IN RATS WITH A  
28-DAY RECOVERY

**STUDY NUMBER**

WIL-189216

**TEST GUIDELINE**

OECD Guideline 408

**STUDY DIRECTOR**

Matthew C. Haas, BA, LAT

**STUDY INITIATION DATE**

3 July 2008

**STUDY COMPLETION DATE**

5 October 2009

**PERFORMING LABORATORY**

WIL Research Laboratories, LLC  
1407 George Road  
Ashland, Ohio 44805-8946  
U.S.A.

**WORK REQUEST, SERVICE CODE**

WR 17751, SC 1026

**SPONSOR LABORATORY PROJECT ID**

DuPont-17751-1026

**SPONSOR**

E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898

**TRADE SECRET**

***Study Title***

Cross-Species Comparison of FRD-902 Plasma Pharmacokinetics in the Rat and Primate  
Following Intravenous Dosing

**AUTHOR:** Shawn A. Gannon, B.S.

**ORIGINAL REPORT**

**COMPLETED:** December 8, 2008

**REPORT REVISION 1**

**COMPLETED:** February 2, 2009

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-17751-1579

**WORK REQUEST NUMBER:** 17751

**SERVICE CODE NUMBER:** 1579

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

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**STUDY TITLE:** H-28548: Early Life-Stage Toxicity to Rainbow Trout,  
*Oncorhynchus mykiss*

**TEST GUIDELINES:** U.S. EPA, OPPTS 850.1400: Fish Early-Life Stage Toxicity  
Test, *Ecological Effects Test Guidelines* (Public Draft, 1996)

OECD Guideline for Testing of Chemicals  
Section 2 (Part 210) (1992)

**AUTHOR:** Robert A. Hoke, Ph.D.

**STUDY COMPLETED ON:** November 15, 2010

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
for Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
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**LABORATORY PROJECT ID:** DuPont-18405-217

**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 217

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.



March 11, 2010

Robert Hoke  
E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898

RE: Report: DuPont D-18405-336, WR 18405, SC 333

Dear Mr. Hoke,

The following is a summary of the findings for the study: H-28548: A Pilot Reproduction Study with the Northern Bobwhite Quail, *Colinus virginianus* (Wildlife International Ltd. Project No.: 112-651). The study evaluated the effects upon adult northern bobwhite quail of dietary exposure to H-28548 over a six-week period. Effects on health, weight gain and feed consumption were examined. In addition, the effects of adult exposure to H-28548 on the number of eggs laid, normal development of eggs, viability of the embryos, percent hatchability, offspring survival and egg shell thickness were evaluated.

Three treatment groups, each containing five pairs of northern bobwhite quail, were fed diets containing H-28548 at nominal dietary concentrations of 10, 100 or 1000 ppm. A fourth control group, fed non-treated diet, was maintained concurrently with the treatment groups.

#### METHODS

Test diets were prepared by mixing H-28548 into a premix that was used for weekly preparation of the final diet. Homogeneity of the test substance in the diet was evaluated by collecting six samples from each of the 10 and 1000 ppm treated diets and one sample from the control diet on Day 0 of Week 1. Samples also were collected from the 100 ppm treated diet on Day 0 of Week 1, and from the control and all treatment group diets during Week 6 of the test to measure/verify test concentrations. Additionally, control and treatment group diet samples were collected from the trough feeders on Day 7 of Week 1 to assess stability of the test substance under actual test conditions.

The test birds were acclimated to the facilities and study pens prior to initiation of the test. During the study, all adult birds were observed daily for signs of toxicity or abnormal behavior. A record was maintained of all clinical observations. Adult body weights were measured at test initiation, on Weeks 2, 4, and at adult termination. Feed consumption for each pen was measured weekly throughout the test. At the conclusion of the exposure period, all adult birds were euthanized and necropsied.

Eggs were collected daily from all pens, when available. During Weeks 1 and 2 eggs were counted, then disposed. Eggs produced during Weeks 3 through 6 were counted and those selected for egg shell thickness measurement were removed. The remaining eggs were identified by an alphabetic lot

**TRADE SECRET**

*Study Title*

**H-28548: A REPRODUCTION STUDY WITH THE NORTHERN BOBWHITE  
QUAIL (*COLINUS VIRGINIANUS*)**

*Test Guidelines*

OECD Guideline 206, Avian Reproduction Test; U.S. EPA Ecological Effects Test Guidelines, OPPTS 850.2300 (draft), Avian Reproduction Test; and U.S. EPA, Pesticide Assessment, Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms, Subsection 71-4

*Authors*

Diana L. Temple  
Kathy H. Martin  
Joann B. Beavers  
Mark Jaber

*Date Study Initiated*

March 23, 2010

*Date Study Completed*

November 23, 2010

*Performing Laboratory*

Wildlife International, Ltd.  
8598 Commerce Drive  
Easton, Maryland 21601  
U.S.A.

*Sponsor*

E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

*DuPont Project Identification Numbers*

DuPont Report: D-18405-338  
Work Request No.: 18405  
Service Code: 338

*Wildlife International Ltd. Study Number*

112-652

**TRADE SECRET**

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**FINAL REPORT**

Volume 1 of 2 (Text, Tables, and Appendices A-D)

**STUDY TITLE**

AN ORAL (GAVAGE) PRENATAL  
DEVELOPMENTAL TOXICITY STUDY OF H-28548 IN RATS

**STUDY NUMBER**

WIL-189223

**DATA REQUIREMENT**

OPPTS Guideline 870.3700  
OECD Guideline 414

**STUDY DIRECTOR**

Tammye L. Edwards, B.S., L.A.T.

**STUDY INITIATION DATE**

12 October 2009

**STUDY COMPLETION DATE**

2 July 2010

**PERFORMING LABORATORY**

WIL Research Laboratories, LLC  
1407 George Road  
Ashland, Ohio 44805-8946  
U.S.A.

**SPONSOR STUDY NUMBER**

18405-841

**SPONSOR**

E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.



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**STUDY TITLE:** H-28548: Toxicokinetic Study in Pregnant Rats

**AUTHOR:** Susan M. Munley, M.A.

**ORIGINAL REPORT**

**COMPLETED:** March 29, 2011

**REPORT REVISION 1**

**COMPLETED:** April 11, 2011

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
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Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-18405-849

**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 849

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

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**STUDY TITLE:** H-28548: Absorption, Distribution, Metabolism, and  
Elimination in the Rat

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.7485 (1998)

**AUTHOR:** William J. Fasano, Sr., B.S.

**ORIGINAL REPORT**

**COMPLETED:** November 3, 2010

**REPORT REVISION 1**

**COMPLETED:** April 21, 2011

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
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Wilmington, Delaware 19803  
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**LABORATORY PROJECT ID:** DuPont-18405-1017

**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1017

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

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**FINAL REPORT**

Contents: Volume 1 of 7  
Text, Summary Tables, and Appendices A - D  
Pages in Volume 1: 233

Study Title: An Oral (Gavage) Reproduction/Developmental  
Toxicity Screening Study of H-28548 in Mice

Study Number: WIL-189225

Study Director: Tammye L. Edwards, B.S., L.A.T.

Data Requirements: U.S. EPA OPPTS Guideline 870.3550 and OECD  
Guideline 421

Study Initiation Date: 4 January 2010

Study Completion Date: 29 December 2010

Performing Laboratory: WIL Research Laboratories, LLC  
1407 George Road  
Ashland, Ohio 44805-8946  
U.S.A.

Sponsor Study Number: 18405-1037

Sponsor: E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

*Study Title*

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 1 of 13**

**NUMBER OF PAGES IN VOLUME:** 233

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

**APPLICANT/SPONSOR:** E.I. du Pont de Nemours and Company  
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**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1238

**MPI RESEARCH STUDY NUMBER:** 125-141

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**TRADE SECRET**

***Study Title***

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 2 of 13**

**NUMBER OF PAGES IN VOLUME:** 245

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

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**TRADE SECRET**

*Study Title*

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 3 of 13**

**NUMBER OF PAGES IN VOLUME:** 335

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

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**TRADE SECRET**

*Study Title*

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 4 of 13**

**NUMBER OF PAGES IN VOLUME:** 292

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

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**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1238

**MPI RESEARCH STUDY NUMBER:** 125-141

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**TRADE SECRET**

*Study Title*

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 5 of 13**

**NUMBER OF PAGES IN VOLUME:** 292

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

**APPLICANT/SPONSOR:** E.I. du Pont de Nemours and Company  
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**PERFORMING LABORATORY:** MPI Research, Inc.  
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**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1238

**MPI RESEARCH STUDY NUMBER:** 125-141

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**TRADE SECRET**

***Study Title***

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 6 of 13**

**NUMBER OF PAGES IN VOLUME:** 338

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

**APPLICANT/SPONSOR:** E.I. du Pont de Nemours and Company  
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**PERFORMING LABORATORY:** MPI Research, Inc.  
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**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1238

**MPI RESEARCH STUDY NUMBER:** 125-141

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**TRADE SECRET**

*Study Title*

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 8 of 13**

**NUMBER OF PAGES IN VOLUME:** 351

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

**APPLICANT/SPONSOR:** E.I. du Pont de Nemours and Company  
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**WORK REQUEST NUMBER:** 18405

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**TRADE SECRET**

*Study Title*

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 9 of 13**

**NUMBER OF PAGES IN VOLUME:** 351

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

**APPLICANT/SPONSOR:** E.I. du Pont de Nemours and Company  
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**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1238

**MPI RESEARCH STUDY NUMBER:** 125-141

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**TRADE SECRET**

*Study Title*

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 10 of 13**

**NUMBER OF PAGES IN VOLUME:** 351

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

**APPLICANT/SPONSOR:** E.I. du Pont de Nemours and Company  
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**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1238

**MPI RESEARCH STUDY NUMBER:** 125-141

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**TRADE SECRET**

*Study Title*

**H-28548: COMBINED CHRONIC TOXICITY/ONCOGENICITY  
STUDY 2-YEAR ORAL GAVAGE STUDY IN RATS**

Laboratory Project ID: DuPont-18405-1238

**Volume 12 of 13**

**NUMBER OF PAGES IN VOLUME:** 351

- TEST GUIDELINES:**
- U.S. EPA Health Effects Test Guidelines OPPTS 870.4300 Combined Chronic Toxicity/Carcinogenicity (1998)
  - OECD Guidelines for the Testing of Chemicals Section 4 (No. 453) Health Effects (2009)
  - JMAFF Japan Agricultural Chemicals Regulation Law 12 Nousan No. 8147 (2000)
  - EEC Methods for the Determination of Toxicity Method B.33 Combined Chronic/Carcinogenicity test, Directive 88/302/EC (1988)

**AUTHOR:** Lisa Craig, B.S.

**STUDY COMPLETED ON:** March 28, 2013

**APPLICANT/SPONSOR:** E.I. du Pont de Nemours and Company  
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**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1238

**MPI RESEARCH STUDY NUMBER:** 125-141

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**TRADE SECRET**

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**STUDY TITLE:** H-28548: Subchronic Toxicity  
90-Day Gavage Study in Mice

**TEST GUIDELINES:** OECD Guideline for the Testing of Chemicals  
Section 4 (Part 408) (1998)

**AUTHOR:** Susan A. MacKenzie, V.M.D., Ph.D., DABT

**STUDY COMPLETED ON:** February 19, 2010

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
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Newark, Delaware 19714  
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**LABORATORY PROJECT ID:** DuPont-18405-1307

**WORK REQUEST NUMBER:** 18405

**SERVICE CODE NUMBER:** 1307

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
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**TRADE SECRET**

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**STUDY TITLE:** H-28548: Absorption, Distribution, Metabolism, and  
Elimination in the Mouse

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.7485 (1998)

**AUTHOR:** William J. Fasano, Sr., B.S.

**ORIGINAL REPORT**

**COMPLETED:** November 3, 2010

**REPORT REVISION 1**

**COMPLETED:** April 21, 2011

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
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E.I. du Pont de Nemours and Company  
DuPont Experimental Station (CCAS)  
Wilmington, Delaware 19803  
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**LABORATORY PROJECT ID:** DuPont-18647-1017

**WORK REQUEST NUMBER:** 18647

**SERVICE CODE NUMBER:** 1017

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.



**TRADE SECRET**

*Study Title*

H-27529:  
Bacterial Reverse Mutation Test

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.5100 (1998)

OECD Guidelines for the Testing of Chemicals  
Section 4 (Part 471) (1998)

EC Commission Directive 2000/32/EC Annex 4D-B.13/14  
Number L 136

**AUTHOR:** Abby Myhre, B.S.

**ORIGINAL REPORT**

**COMPLETED:** May 31, 2006

**REPORT REVISION 1**

**COMPLETED:** February 22, 2008

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-19713

**WORK REQUEST NUMBER:** 16540

**SERVICE CODE NUMBER:** 500

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

***Study Title***

H-27529:  
*In Vitro* Mammalian Chromosome Aberration Test in Chinese Hamster Ovary Cells

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.5375 (1998)

OECD Guidelines for the Testing of Chemicals  
Section 4 (Part 473) (1998)

EC Commission Directive 2000/32/EC Annex 4A-B10  
Number L 136

**ORIGINAL REPORT AUTHOR:** Christine M. Glatt, M.S.

**REPORT REVISION 1 AUTHOR:** Kyle P. Glover, B.A.

**ORIGINAL REPORT**

**COMPLETED:** June 27, 2006

**REPORT REVISION 1**

**COMPLETED:** February 25, 2008

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-19714

**WORK REQUEST NUMBER:** 16540

**SERVICE CODE NUMBER:** 531

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

*Study Title*

H-27529: Local Lymph Node Assay (LLNA) in Mice

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.2600 (2003)

OECD Guideline for the Testing of Chemicals  
Section 4 (Part 429) (2001)

**AUTHOR:** Denise Hoban, B.A, MLT (ASCP)

**STUDY COMPLETED ON:** June 9, 2006

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
Haskell<sup>SM</sup> Laboratory for Health and Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-19897

**WORK REQUEST NUMBER:** 16573

**SERVICE CODE NUMBER:** 1234

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

*Study Title*

H-28072: Local Lymph Node Assay (LLNA) in Mice

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.2600 (2003)

OECD Guideline for the Testing of Chemicals  
Section 4 (Part 429) (2001)

**AUTHOR:** Denise Hoban, B.A, MLT (ASCP)

**ORIGINAL REPORT**

**COMPLETED:** July 2, 2007

**REPORT REVISION 1:** October 1, 2007

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
Haskell<sup>SM</sup> Laboratory for Health and Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-22616

**WORK REQUEST NUMBER:** 17199

**SERVICE CODE NUMBER:** 1234

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

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**STUDY TITLE:** H-28072: *In Vitro* Mammalian Chromosome Aberration Test  
in Chinese Hamster Ovary Cells

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines, OPPTS 870.5375  
(1998)

OECD Guidelines for the Testing of Chemicals, Number 473  
(1998)

EC Commission Directive 2000/32/EC Annex 4A-B10  
Number L 136 (2000)

**AUTHOR:** Christine M. Glatt, M.S.

**ORIGINAL REPORT**

**COMPLETED:** July 25, 2007

**REPORT REVISION 1**

**COMPLETED:** September 23, 2009

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-22620

**WORK REQUEST NUMBER:** 17199

**SERVICE CODE NUMBER:** 531

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.



**TRADE SECRET**

*Study Title*

H-28072:  
Bacterial Reverse Mutation Test

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.5100 (1998)

OECD Guideline for the Testing of Chemicals  
Section 4 (Part 471) (1998)

EC Commission Directive 2000/32/EC Annex 4D-B.13/14  
Number L 136

**AUTHOR:** E. Maria Donner, Ph.D.

**ORIGINAL REPORT**

**COMPLETED:** July 26, 2007

**REPORT REVISION 1**

**COMPLETED:** August 13, 2008

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-22734

**WORK REQUEST NUMBER:** 17199

**SERVICE CODE NUMBER:** 500

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

TRADE SECRET

Study Title

H-28072: Unscheduled DNA Synthesis (UDS) Test  
with Mammalian Cells *In Vivo*

Testing Guidelines

ICH S2A document April 24, 1996  
ICH S2B document November 21, 1997  
EC Commission Annex V to Directive 67/548/EEC, Directive 2000/32/EC, B.39  
OECD Guideline for the Testing of Chemicals, Guideline 486 (1998)

Authors

Kamala Pant, M.S.  
Jamie E. Sly

Final Report Date

14 August 2007

Testing Facility

BioReliance  
9630 Medical Center Drive  
Rockville, MD 20850, U.S.A.  
for  
E. I. DuPont de Nemours and Company  
Dupont Haskell Laboratory  
P.O. Box, 50, 1090 Elkton Road  
Newark, DE 19714-0050, U.S.A.

BioReliance Study Number

AC03GE.381.BTL

Work Request No:

17319

Service Code

484

**TRADE SECRET**

**FINAL REPORT**

Study Title

**H-28072: In Vivo Micronucleus and Chromosome Aberration Assay in  
Mouse Bone Marrow Cells**

Testing Guideline

US EPA Health Effects Test Guidelines, OPPTS Guideline 870.5395 and 870.5385 (1998)  
EC Commission Directive 2000/32/EC Annex 4A-B10 No. L 136 (2000)  
OECD Guidelines for Testing of Chemicals Section 4: Health Effects, No. 474 and 475 (1998)

Authors

Ramadevi Gudi, Ph.D.  
Ljubica Krsmanovic, Ph.D.

Study Completion Date

10 October 2007

Testing Facility

BioReliance  
9630 Medical Center Drive  
Rockville, MD 20850, USA

for

E.I. du Pont de Nemours and Company  
DuPont Haskell Laboratory  
P.O. Box 50  
1090 Elkton Road  
Newark, DE 19714-0050, USA

BioReliance Study Number

AC03GE.123108.BTL

Work Request Number

17319

Service Code

553 and 572

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**HASKELL LABORATORY DISCOVERY TOXICOLOGY GROUP**

**In Vitro Rat Hepatocyte Screen**

WR: 17199  
SERVICE CODE: 1599  
HASKELL#: 28072  
STUDY COMPLETED: 12-Jun-07  
NOTEBOOK #: E-111389-AT

**STUDY DESIGN:**

Test Substance: HFPO Dimer Acid Salt  
Species: Rat  
Strain: CrI:CD<sup>®</sup>(SD)IGS BR  
Gender: Male and Female  
Cell Concentration:  $1 \times 10^6$  cells/mL (clearance incubations)  
 $5 \times 10^6$  cells/mL (biotransformation incubations)  
Reaction Buffer: L-15 medium  
pH: 7.4  
Reaction Volume: 2.5 mL  
Dose Vehicle: Nanopure Water  
Dose Volume: 10  $\mu$ L/mL  
Final Concentration: 2  $\mu$ M = 694 ppb (clearance incubations)  
200  $\mu$ M = 69.4 ppm (biotransformation incubations)  
Replicates/Sex: 3 test, 3 heat-inactivated controls, 1 biotransformation, 1 positive control (4-nonylphenol).  
Time Points: 5, 15, 30, 45, 60, 90, and 120 minutes  
Incubation Temperature: 37°C  
Extraction: 1:2, Sample:Acetonitrile  
Dilution: 1:1, Sample:Nanopure Water  
Final Dilution Factor: 6x  
Analytical: LC/MS

**OBJECTIVE:**

To estimate metabolic clearance of test compound in rat hepatocytes and extrapolate results to whole animal and to identify metabolites and describe probable metabolic pathways for the compound tested.

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DUPONT HASKELL GLOBAL CENTERS FOR HEALTH & ENVIRONMENTAL  
SCIENCES

Discovery Toxicology Group

**Repeated Dose Oral Toxicity 7-Day Gavage Study in Rats**

WORK REQUEST: 17474  
SERVICE CODE: 1654  
HASKELL NUMBER: 28308  
DUPONT REPORT NUMBER: 24009  
TESTING SOP NUMBER: DC005-T-001  
STUDY START DATE: 03-October-07  
STUDY END DATE: 1-December-07  
NOTEBOOK(s): E-111389-BE

STUDY DIRECTOR: Diane L. Nabb, Staff Toxicologist  
REPORT ISSUE DATE: February 14, 2008

OBJECTIVE

To evaluate potential subacute toxicity and kinetic behavior of the test substance when administered by oral gavage to male and female rats for 7 consecutive days.

STUDY DESIGN

Test Substance:	HFPO Dimer Acid Ammonium Salt
Lot/Batch Number:	E1131181-6
Purity:	86.6% (doses were corrected for purity)
Species:	Rat
Strain:	CrI:CD(SD)
Gender:	Male and Female
Age at start:	~6 weeks
Group Size:	Control 5 males, 5 females Low dose 8 males, 8 females (5/sex Main study, 3/sex Metabolism) Mid dose 5 males, 5 females (5/sex Main study) High dose 5 males, 5 females (5/sex Main study)
Dose Levels:	0, 30, 300, 1000 mg/kg Main study 30 mg/kg for Metabolism animals
Route:	Oral gavage
Dosing Volume:	10 mL/kg Main study and Metabolism animals



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**DUPONT HASKELL GLOBAL CENTERS FOR HEALTH & ENVIRONMENTAL  
SCIENCES**

**Discovery Toxicology Group**

**Repeated Dose Oral Toxicity 7-Day Gavage Study in Mice**

WORK REQUEST:	17533
SERVICE CODE:	1655
HASKELL NUMBER:	28393
DUPONT REPORT NUMBER:	24010
TESTING SOP NUMBER:	DC007-T-001
STUDY START DATE:	10/26/07
STUDY END DATE:	12/14/07
NOTEBOOK(s):	E-111389-BG
STUDY DIRECTOR:	Diane Nabb, Staff Scientist

**STUDY DESIGN:**

Test Substance:	Compound 48
Batch:	E111934-20
Purity:	>97%
Species:	Mouse
Strain:	CrI:CD1(ICR)
Gender:	Male
Age at start:	~6 weeks
Group Size:	5 animals/group
Dose Levels:	30mg/kg H#28393 dose – 5 animals
Route:	30 mg/kg, only one dose level
Dosing Volume:	Oral gavage
Dose Vehicle:	10 ml/kg
Dosing Frequency:	Water
	Daily, Day 0-Day 6

**OBJECTIVE:**

Determine target organ toxicity.

**PARAMETERS:**

Clinical signs, body weight, necropsy, organ weight, and histopathology

**TRADE SECRET**

***Study Title***

FRD-903: Corrositex<sup>®</sup> *In Vitro* Test

**AUTHOR:** Carol Carpenter, B.A.

**STUDY COMPLETED ON:** September 25, 2007

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
for Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-24019

**WORK REQUEST NUMBER:** 17473

**SERVICE CODE NUMBER:** 1302

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

*Study Title*

FRD-902: Acute Dermal Irritation Study in Rabbits

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.2500 (1998)

OECD Guideline for the Testing of Chemicals  
Section 4 (Part 404) (2002)

EEC Methods for the Determination of Toxicity  
Method B.4 Directive 92/69/EEC (1992)

**AUTHOR:** Carol Carpenter, B.A.

**STUDY COMPLETED ON:** November 21, 2007

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
for Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-24030

**WORK REQUEST NUMBER:** 17474

**SERVICE CODE NUMBER:** 1008

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

*Study Title*

FRD-902: Acute Dermal Toxicity Study in Rats

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.1200 (1998)

OECD Guideline for the Testing of Chemicals  
Section 4 (Part 402) (1987)

EEC Methods for the Determination of Toxicity  
Method B.3 Directive 92/69/EEC (1992)

**AUTHOR:** Carol Carpenter, B.A.

**STUDY COMPLETED ON:** November 28, 2007

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
for Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-24113

**WORK REQUEST NUMBER:** 17474

**SERVICE CODE NUMBER:** 673

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

**TRADE SECRET**

*Study Title*

FRD-902: Acute Eye Irritation Study in Rabbits

**TEST GUIDELINES:** U.S. EPA Health Effects Test Guidelines  
OPPTS 870.2400 (1998)

OECD Guideline for the Testing of Chemicals  
Section 4 (Part 405) (2002)

EEC Methods for the Determination of Toxicity  
Method B.5 Directive 92/69/EEC (1992)

**AUTHOR:** Carol Carpenter, B.A.

**STUDY COMPLETED ON:** December 14, 2007

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
for Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-24114

**WORK REQUEST NUMBER:** 17474

**SERVICE CODE NUMBER:** 602

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.



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DUPONT HASKELL GLOBAL CENTERS FOR HEALTH & ENVIRONMENTAL  
SCIENCES

Discovery Toxicology Group

**Repeated Dose Oral Toxicity 7-Day Gavage Study in Rats**

WORK REQUEST: 17473  
SERVICE CODE: 1654  
HASKELL NUMBER: 28307  
DUPONT REPORT NUMBER: 24116  
TESTING SOP NUMBER: DC005-T-001  
STUDY START DATE: 11-October-07  
STUDY END DATE: 12-December-07  
NOTEBOOK(s): E-111389-BF

STUDY DIRECTOR: Diane L. Nabb, Staff Toxicologist  
REPORT ISSUE DATE: February 14, 2008

OBJECTIVE

To evaluate potential subacute toxicity and kinetic behavior of the test substance when administered by oral gavage to male and female rats for 7 consecutive days.

STUDY DESIGN

Test Substance:	HFPO Dimer Acid
Lot/Batch Number:	E112820-46MC
Purity:	99% (doses were corrected for purity)
Species:	Rat
Strain:	CrI:CD(SD)
Gender:	Male and Female
Age at start:	~6 weeks
Group Size:	Control 5 males, 5 females Low dose 8 males, 8 females (5/sex Main study, 3/sex Metabolism) Mid dose 5 males, 5 females (5/sex Main study) High dose 5 males, 5 females (5/sex Main study)
Dose Levels:	0, 30, 100, 300 mg/kg Main study 30 mg/kg for Metabolism animals
Route:	Oral gavage
Dosing Volume:	10 mL/kg Main study and Metabolism animals

**TRADE SECRET**

***Study Title***

FRD-902: Acute Oral Toxicity Study in Mice - Up-and-Down Procedure

**TEST GUIDELINES:** U.S. EPA Health Effect Test Guidelines  
OPPTS 870.1100 (2002)

OECD Guideline for the Testing of Chemicals  
Section 4 (Part 425) (2001)

**AUTHOR:** Carol Carpenter, B.A.

**STUDY COMPLETED ON:** November 29, 2007

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
for Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-24126

**WORK REQUEST NUMBER:** 17474

**SERVICE CODE NUMBER:** 835

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

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DUPONT HASKELL GLOBAL CENTERS FOR HEALTH & ENVIRONMENTAL  
SCIENCES  
Discovery Toxicology Group

**Biopersistence and Pharmacokinetic Screen in the Rat**

WORK REQUEST: 17199  
SERVICE CODE: 415  
HASKELL NUMBER: 28072  
DUPONT REPORT NUMBER: 24281  
TESTING SOP NUMBER: BT004-T-002  
STUDY START DATE: 13-June-2007  
STUDY END DATE: 21-June-2007  
NOTEBOOK(s): E-111389-AV

WORK BY: Scott M. Krenzel, Associate Scientist  
Michael P. Mawn, Senior Research Chemist  
STUDY DIRECTOR: Shawn A. Gannon, Senior Staff Toxicologist  
REPORT ISSUE DATE: 13-February-2008

STUDY DESIGN

Test Substance:	HFPO Dimer Acid Ammonium Salt
Lot/Batch Number:	111593-74
Purity:	84.5% (dose corrected for purity)
Species:	Rat
Strain:	CrI:CD(SD)
Vendor:	Charles River Laboratories, Raleigh, North Carolina, U.S.A.
Sex:	Male and Female
Route:	Oral
Age at Study Start:	7-12 weeks
Total Group Size:	3/sex/dose level
Dose Frequency:	Single dose
Dose Vehicle:	Water
Dose:	Low dose 10 mg/kg, high dose 30 mg/kg
Dose Volume:	4 mL/kg
Blood Sample Time Points:	0, 0.25, 0.5, 1, 2, 4, 8, 12, 24, 48, 72, 96, 120, 144, and 168 hours

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DUPONT HASKELL GLOBAL CENTERS FOR HEALTH & ENVIRONMENTAL  
SCIENCES

Discovery Toxicology Group

**Biopersistence and Pharmacokinetic Screen in the Rat**

WORK REQUEST: 17473  
SERVICE CODE: 415  
HASKELL NUMBER: 28307  
DUPONT REPORT NUMBER: 24286  
TESTING SOP NUMBER: BT004-T-002  
STUDY START DATE: 2-October-2007  
STUDY END DATE: 10-October-2007  
NOTEBOOK(s): E-104276-CZ

WORK BY: Critical Path Services  
STUDY DIRECTOR: Shawn A. Gannon, Senior Staff Toxicologist  
REPORT ISSUE DATE: 13-February-2008

STUDY DESIGN

Test Substance:	HFPO Dimer Acid
Lot/Batch Number:	E112820-46MC
Purity:	98%
Species:	Rat
Strain:	CrI:CD(SD)
Vendor:	Charles River Laboratories, Raleigh, North Carolina, U.S.A.
Sex:	Male and Female
Route:	Oral
Age at Study Start:	7-12 weeks
Total Group Size:	3/sex/dose level
Dose Frequency:	Single dose
Dose Vehicle:	Water
Dose:	Low dose 10 mg/kg, high dose 30 mg/kg
Dose Volume:	4 mL/kg
Blood Sample Time Points:	0, 0.25, 0.5, 1, 2, 4, 8, 12, 24, 48, 72, 96, 120, 144, and 168 hours

**TRADE SECRET**

**FINAL REPORT**

Volume 1 of 4  
(Text, Figures 1-4, Tables 1-48 and Appendix A [Tables A1-A5])

**STUDY TITLE**

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY  
OF H-28397 IN RATS WITH A 28-DAY RECOVERY

**STUDY NUMBER**

WIL-189205

**DATA REQUIREMENT**

OECD Guideline 407

**STUDY DIRECTOR**

Matthew C. Haas, BA, LAT

**STUDY INITIATION DATE**

16 November 2007

**STUDY COMPLETION DATE**

22 August 2008

**PERFORMING LABORATORY**

WIL Research Laboratories, LLC  
1407 George Road  
Ashland, Ohio 44805-8946  
U.S.A.

**SPONSOR WORK REQUEST, SERVICE CODE**

WR 17568, SC 1023

**SPONSOR STUDY NUMBER**

DuPont-24447

**SPONSOR**

E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for Health and Environmental Sciences  
1090 Elkton Road, P.O. Box 50  
Newark, Delaware 19714  
U.S.A.



**FINAL REPORT**

Volume 2 of 4  
(Appendix A [Tables A6-A23])

**STUDY TITLE**

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY  
OF H-28397 IN RATS WITH A 28-DAY RECOVERY

**STUDY NUMBER**

WIL-189205

**DATA REQUIREMENT**

OECD Guideline 407

**STUDY DIRECTOR**

Matthew C. Haas, BA, LAT

**STUDY INITIATION DATE**

16 November 2007

**STUDY COMPLETION DATE**

22 August 2008

**PERFORMING LABORATORY**

WIL Research Laboratories, LLC  
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Ashland, Ohio 44805-8946  
U.S.A.

**SPONSOR WORK REQUEST, SERVICE CODE**

WR 17568, SC 1023

**SPONSOR STUDY NUMBER**

DuPont-24447

**SPONSOR**

E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for Health and Environmental Sciences  
1090 Elkton Road, P.O. Box 50  
Newark, Delaware 19714  
U.S.A.



**FINAL REPORT**

Volume 3 of 4  
(Appendices A [Tables A24-A58] and B)

**STUDY TITLE**

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY  
OF H-28397 IN RATS WITH A 28-DAY RECOVERY

**STUDY NUMBER**

WIL-189205

**DATA REQUIREMENT**

OECD Guideline 407

**STUDY DIRECTOR**

Matthew C. Haas, BA, LAT

**STUDY INITIATION DATE**

16 November 2007

**STUDY COMPLETION DATE**

22 August 2008

**PERFORMING LABORATORY**

WIL Research Laboratories, LLC  
1407 George Road  
Ashland, Ohio 44805-8946  
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**SPONSOR WORK REQUEST, SERVICE CODE**

WR 17568, SC 1023

**SPONSOR STUDY NUMBER**

DuPont-24447

**SPONSOR**

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U.S.A.

**FINAL REPORT**

Volume 4 of 4  
(Appendices C - I)

**STUDY TITLE**

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY  
OF H-28397 IN RATS WITH A 28-DAY RECOVERY

**STUDY NUMBER**

WIL-189205

**DATA REQUIREMENT**

OECD Guideline 407

**STUDY DIRECTOR**

Matthew C. Haas, BA, LAT

**STUDY INITIATION DATE**

16 November 2007

**STUDY COMPLETION DATE**

22 August 2008

**PERFORMING LABORATORY**

WIL Research Laboratories, LLC  
1407 George Road  
Ashland, Ohio 44805-8946  
U.S.A.

**SPONSOR WORK REQUEST, SERVICE CODE**

WR 17568, SC 1023

**SPONSOR STUDY NUMBER**

DuPont-24447

**SPONSOR**

E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for Health and Environmental Sciences  
1090 Elkton Road, P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**TRADE SECRET**

**FINAL REPORT**

Volume 1 of 4  
(Text, Figures 1-4, Tables 1-46 and Appendix A [Tables A1-A5])

**STUDY TITLE**

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY  
OF H-28397 IN MICE WITH A 28-DAY RECOVERY

**STUDY NUMBER**

WIL-189207

**DATA REQUIREMENT**

OECD Guideline 407

**STUDY DIRECTOR**

Matthew C. Haas, BA, LAT

**STUDY INITIATION DATE**

3 December 2007

**STUDY COMPLETION DATE**

29 August 2008

**PERFORMING LABORATORY**

WIL Research Laboratories, LLC  
1407 George Road  
Ashland, Ohio 44805-8946

**SPONSOR WORK REQUEST, SERVICE CODE**

WR 17568, SC 1317

**SPONSOR STUDY NUMBER**

DuPont-24459

**SPONSOR**

E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for Health and Environmental Sciences  
1090 Elkton Rd, P.O. Box 50  
Newark, Delaware 19714

**FINAL REPORT**

Volume 2 of 4  
(Appendix A [Tables A6-A22])

**STUDY TITLE**

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY  
OF H-28397 IN MICE WITH A 28-DAY RECOVERY

**STUDY NUMBER**

WIL-189207

**DATA REQUIREMENT**

OECD Guideline 407

**STUDY DIRECTOR**

Matthew C. Haas, BA, LAT

**STUDY INITIATION DATE**

3 December 2007

**STUDY COMPLETION DATE**

29 August 2008

**PERFORMING LABORATORY**

WIL Research Laboratories, LLC  
1407 George Road  
Ashland, Ohio 44805-8946

**SPONSOR WORK REQUEST, SERVICE CODE**

WR 17568, SC 1317

**SPONSOR STUDY NUMBER**

DuPont-24459

**SPONSOR**

E.I. du Pont de Nemours and Company  
DuPont Haskell<sup>SM</sup> Global Centers for Health and Environmental Sciences  
1090 Elkton Rd, P.O. Box 50  
Newark, Delaware 19714

**FINAL REPORT**

Volume 3 of 4  
(Appendix A [Tables A23-A47] And Appendix B)

**STUDY TITLE**

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY  
OF H-28397 IN MICE WITH A 28-DAY RECOVERY

**STUDY NUMBER**

WIL-189207

**DATA REQUIREMENT**

OECD Guideline 407

**STUDY DIRECTOR**

Matthew C. Haas, BA, LAT

**STUDY INITIATION DATE**

3 December 2007

**STUDY COMPLETION DATE**

29 August 2008

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**FINAL REPORT**

Volume 4 of 4  
(Appendices C - J)

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DUPONT HASKELL GLOBAL CENTERS FOR HEALTH & ENVIRONMENTAL  
SCIENCES  
Discovery Toxicology Group

**Repeated Dose Oral Toxicity 7-Day Gavage Study in Male Mice**

WORK REQUEST: 17473  
SERVICE CODE: 1655  
HASKELL NUMBER: 28307  
DUPONT REPORT NUMBER: 25281  
TESTING SOP NUMBER: DC007-T-001  
STUDY START DATE: 26-October-07  
STUDY END DATE: 14-December-07  
NOTEBOOK(s): E-111389-BG

STUDY DIRECTOR: Diane L. Nabb, Staff Toxicologist  
REPORT ISSUE DATE: February 14, 2008

OBJECTIVE

To determine target organ toxicity in mice exposed to H-28307 orally for 7 days.

STUDY DESIGN

Test Substance:	HFPO Dimer Acid
Lot/Batch Number:	E112820-46MC
Purity:	99%
Species:	Mouse
Strain:	CrI:CD1(ICR)
Gender:	Male
Age at start:	~6 weeks
Group Size:	5 males
Dose Levels:	30 mg/kg
Route:	Oral gavage
Dosing Volume:	10 mL/kg
Dose Vehicle:	Water
Dosing Frequency:	Daily, Day 0-Day 6

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Determination of a permeability coefficient (Kp) for H-28308 using human and rat skin mounted in an in vitro static diffusion cell

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This study was conducted under Work Request 17474, Service Code 1588.

## MATERIAL AND METHODS

Samples of human and rat skin were dermatomed to approximately 450  $\mu\text{m}$  and mounted onto an in vitro static diffusion cell (Figure 1). The donor and receptor chambers were filled with saline and the water-jacketed cells maintained at 32°C using a re-circulating water bath. Following a brief equilibration, membrane integrity was confirmed using electrical impedance (n=3 replicates per species). Saline was then removed from the donor chamber and the test material H-28308, an aqueous solution of HFPO dimer acid ammonium salt (86%), which had been further diluted with water to a concentration of 124 mg/mL, was applied to the epidermal surface via the donor chamber as an infinite dose (pilot experiments had suggested application of the neat test substance would likely degrade the barrier properties of the skin, so a more dilute sample was used). The donor chamber was then occluded with Parafilm® and serial receptor fluid samples (100  $\mu\text{L}$ ) were collected at 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 12 and 24 hours and analyzed for HFPO anion by LC/MS/MS (329>285 m/z). The cumulative amount of HFPO anion detected in the receptor fluid at each sampling time point was normalized to the exposure area (0.64  $\text{cm}^2$ ) and the results plotted as the cumulative amount penetrated ( $\mu\text{g}/\text{cm}^2$ ) versus time (in hours) to produce a penetration profile. A permeability coefficient (Kp in  $\text{cm}/\text{h}$ ) was calculated by dividing the penetration rate or slope of the line at steady-state ( $\mu\text{g}/\text{cm}^2/\text{h}$ ) by the concentration of the applied chemical ( $\mu\text{g}/\text{cm}^3$ ).

Study Director: William J. Fasano, Sr., B.S.  
Senior Research Toxicologist

Report Issue Date: February 27, 2008

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DUPONT HASKELL GLOBAL CENTERS FOR HEALTH & ENVIRONMENTAL  
SCIENCES

Discovery Toxicology Group

**Biopersistence and Pharmacokinetic Screen in the Mouse**

WORK REQUEST: 17474  
SERVICE CODE: 417  
HASKELL NUMBER: 28308  
DUPONT REPORT NUMBER: 25300  
TESTING SOP NUMBER: BT004-T-002  
STUDY START DATE: 17-March-2008  
STUDY END DATE: 26-March-2008  
NOTEBOOK(s): E-111389-BY

WORK BY: Michael P. Mawn, Senior Research Chemist  
Richard Rossi, Associate Scientist  
STUDY DIRECTOR: Shawn A. Gannon, Senior Staff Toxicologist  
REPORT ISSUE DATE: July 31, 2008

STUDY DESIGN

Test Substance:	FRD-902
Lot/Batch Number:	E1131181-6
Purity:	86% (dose corrected for purity)
Species:	Mouse
Strain:	Crl:CD1(ICR)
Vendor:	Charles River Laboratories, Raleigh, North Carolina, U.S.A.
Sex:	Male and Female
Route:	Oral
Age at Study Start:	7-12 weeks
Total Group Size:	3/sex/dose level/time point
Dose Frequency:	Single dose
Dose Vehicle:	Water
Dose:	Low dose 10 mg/kg, high dose 30 mg/kg
Dose Volume:	4 mL/kg
Blood Sample Time Points:	0, 0.25, 0.5, 1, 2, 4, 8, 12, 24, 48, 72, 96, 120, 144, and 168 hours

**TRADE SECRET**

*Study Title*

FRD-903: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure

**TEST GUIDELINES:** U.S. EPA Health Effect Test Guidelines  
OPPTS 870.1100 (2002)

OECD Guideline for the Testing of Chemicals  
Section 4 (Part 425) (2001)

**AUTHOR:** Carol Carpenter, B.A.

**STUDY COMPLETED ON:** October 13, 2008

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers  
for Health & Environmental Sciences  
P.O. Box 50  
Newark, Delaware 19714  
U.S.A.

**LABORATORY PROJECT ID:** DuPont-25875

**WORK REQUEST NUMBER:** 17644

**SERVICE CODE NUMBER:** 834

**SPONSOR:** E.I. du Pont de Nemours and Company  
Wilmington, Delaware 19898  
U.S.A.

TRADE SECRET

Study Title

H-28548: *In Vitro* Mammalian Cell Gene Mutation Test  
(L5178Y/TK+/- Mouse Lymphoma Assay)

Testing Guidelines

ICH S2A document April 24, 1996  
ICH S2B document November 21, 1997  
OECD Guideline for the Testing of Chemicals, Guideline 476 (1998)  
US EPA Health Effects Test Guidelines, OPPTS 870.5300 (1998)  
EC Commission Directive 2000/32/EC, Annex 4E No. L136

Author

Jane J. Clarke, M.S.

Study Completion Date

25 June 2008

Testing Facility

BioReliance  
9630 Medical Center Drive  
Rockville, MD 20850, USA  
for  
E. I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for Health and Environmental Sciences  
P.O. Box 50  
1090 Elkton Road  
Newark, DE 19714-0050, USA

BioReliance Study Number

AC15UX.704.BTL

Work Request Number

17751

Service Code

1537



Study Title

Approximate Lethal Dose (ALD) of H-21216 in Rats

Laboratory Project ID

Haskell Laboratory Report No. 770-95

Author

M. Scott Karr

Study Completed On

February 26, 1996

Performing Laboratory

E. I. du Pont de Nemours and Company  
Haskell Laboratory for Toxicology and Industrial Medicine  
Elkton Road, P. O. Box 50  
Newark, Delaware 19714

Medical Research No. 10074-001



Study Title

Approximate Lethal Dose (ALD) by  
Skin Absorption of H-21216 in Rabbits

Laboratory Project ID

Haskell Laboratory Report No. 839-95

Author

Tracy A. Filliben

Study Completed On

April 1, 1996

Performing Laboratory

E. I. du Pont de Nemours and Company  
Haskell Laboratory for Toxicology and Industrial Medicine  
P. O. Box 50, Elkton Road  
Newark, Delaware 19714

Medical Research Project No. 10074-001